## Food and Drug Administration, HHS

- (2) *Indications for use.* For the control of pain and inflammation associated with osteoarthritis.
- (3) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[68 FR 42968, July 21, 2003, as amended at 69 FR 69523, Nov. 30, 2004]

## § 520.1380 Methocarbamol tablets.

- (a) Chemical name. 3-(O-Methoxyphenoxy)-1,2-propanediol 1-carbamate.
- (b) *Specifications*. Each tablet contains 500 milligrams of methocarbamol.
- (c) Sponsor. See No. 000856 in  $\S510.600$ (c) of this chapter.
- (d) Conditions of use. (1) The drug is administered to dogs and cats as an adjunct to therapy for acute inflammatory and traumatic conditions of the skeletal muscles in order to reduce muscular spasms.
- (2) Dosage is based upon severity of symptoms and response noted. The usual initial dose in 60 milligrams per pound of body weight in two or three equally divided doses followed by 30 to 60 milligrams per pound of body weight each following day, usually not to exceed 14 to 21 days.
- (3) For use only by or on the order of a licensed veterinarian.

[40 FR 13838, Mar. 27, 1975, as amended at 67 FR 67521, Nov. 6, 2002]

## $\S 520.1390$ (S)-methoprene.

- (a) *Specifications*. Each capsule contains 154, 308, or 462 milligrams (mg) of (S)-methoprene.
- (b) Sponsor. See No. 011536 in \$510.600(c) of this chapter.
  - (c) [Reserved]
- (d) Conditions of use—(1) Amount. Capsules are given orally, once per week at the recommended minimum dosage of 10 mg of (S)-methoprene per pound of body weight (22 mg/kilograms).
- (2) Indications for use. For oral use in dogs, 9 weeks of age and older and 4 pounds body weight or greater, for the prevention and control of flea populations. (S)-methoprene prevents and controls flea populations by preventing the development of flea eggs but does not kill adult fleas. Concurrent use of

insecticides may be necessary for adequate control of adult fleas.

[65 FR 20730, Apr. 18, 2000]

## $\S 520.1408$ Methylprednisolone tablets.

- (a) *Specifications.* Each table contains 1, 2, or 4 milligrams of methylprednisolone.
- (b) *Sponsor*. See No. 000009 in §510.600(c) of this chapter for use of 1- and 4-milligram tablets; see No. 000010 for use of 1- and 2-milligram tablets.
- (c) NAS/NRC status. The conditions of use have been NAS/NRC reviewed and found effective. NADA's for approval of drugs for these conditions of use need not include effectiveness data specified by §514.111 of this chapter, but may require bioequivalency and safety information.
- (d) Special consideration. (1) Clinical and experimental data have demonstrated that corticosteroids administered orally or parenterally to animals may induce the first stage of parturition when administered during the last trimester of pregnancy and may precipitate premature parturition followed by dystocia, fetal death, retained placenta, and metritis.
- therapy Systemic methylprednisolone is contraindicated in animals with arrested tuberculosis, peptic ulcer, acute psychoses, or cushingoid syndrome. The presence of active tuberculosis. diabetes. osteoporosis, chronic psychotic reacpredisposition tions. thrombophlebitis, hypertension, congestive heart failure, or renal insufficiency necessitates carefully controlled use of corticosteroids. Some of these conditions occur only rarely in dogs and cats but should be kept in mind.
- (3) Anti-inflammatory action of corticosteroids may mask signs of infection.
- (e) Conditions of use—(1) Amount. Dogs and cats: 5 to 15 pounds, 2 milligrams; 15 to 40 pounds, 2 to 4 milligrams; 40 to 80 pounds, 4 to 8 milligrams.
- (2) Indications for use. For use in dogs and cats as an anti-inflammatory
- (3) *Limitations.* Administer total daily dose orally in equally divided doses 6 to 10 hours apart until response is noted or 7 days have elapsed. When response